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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/524,077

09/21/2005

Shmuel Ben Muvhar

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09/16/2008

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EXAMINER

SIMPSON, SARAH A

ART UNIT

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/524,077	<b>Applicant(s)</b> BEN MUVHAR, SHMUEL	
	<b>Examiner</b> SARAH A. SIMPSON	<b>Art Unit</b> 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 February 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/08/2008; 10/31/2006</u> .                                   | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Priority*

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### *Claim Objections*

2. **Claims 1-6** are objected to because of the following informalities: Claim 1 should read “a passage through which blood may flow” so as not to claim a human body part. Appropriate correction is required.

### *Claim Rejections - 35 USC § 102*

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. **Claims 1-6 and 20-29** are rejected under 35 U.S.C. 102(e) as being anticipated by **Chobotov (US 6,395,019 B2)**.

**Regarding claims 1-4, and 26-29**, Chobotov discloses an inflatable tubular implant comprising: a continuous outer surface (columns 6-7, lines 66-67, 1-3) having a geometry of a tube made of resilient materials (column 7, lines 6-9), at least a portion of which is adapted for contacting a blood vessel and changing configuration upon absorption of fluid (column 7, lines 51-54); and an inner surface defining a passage through which blood flows, wherein the distance between the inner surface and the outer surface is non-uniform along an axis of the tube (fig. 2) and at least a portion of which is hollow and adapted to be inflated (abstract); wherein at least a portion of the implant comprises shape memory materials (column 7, lines 25-31).

**Regarding claim 5**, Chobotov discloses wherein the inner surface is parallel to the longitudinal axis of the flow passage (fig. 2).

**Regarding claim 6**, Chobotov discloses wherein the outer surface is non-parallel to the longitudinal axis of the flow passage (fig. 2).

**Regarding claim 20**, Chobotov discloses an implant comprising: a tubular wall defining a flow passage adapted for encircling a flow of blood through a vessel (fig. 4) and least one wire (52, 53, 54) of varying effective width adapted to at least partially obstruct blood flow (column 8, lines 27-43). It has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense.

**Regarding claims 21-25**, Stinson discloses the implant according to claim 20, wherein there are at least two wires (52, 53, 54) which are interconnected and connected to an object and curve in a plane of the width of the wire (fig. 4).

6. **Claims 7-17** are rejected under 35 U.S.C. 102(b) as being anticipated by **Perrier et al. (US 5,123,918)**.

**Regarding claim 7-12**, Perrier et al. disclose an implant for obstructing blood flow in a blood vessel, the implant comprising: a tubular wall (1) defining a flow passage adapted for encircling a flow of blood through a vessel; two or more positionally adjustable flaps (2) projecting from the wall into the blood flow (figs. 1-6); and two or more guide elements (20, 40, 70) which deform under pressure connecting the flaps, operative to maintain the flaps in a position partially blocking the flow of passage (columns 9-10, lines 13-17, 65-68, 1-4).

**Regarding claims 13 and 17**, Perrier et al. disclose an implant for obstructing blood flow in a blood vessel, the implant comprising: a tubular wall (1) defining a flow passage adapted for encircling a flow of blood through a vessel; and at least two non-overlapping flap (2) projecting from the wall into the blood flow (figs. 1-6).

**Regarding claim 14**, Perrier et al. disclose the implant according to claim 13, wherein the at least one flap is substantially planar with a surface of the tubular wall (fig. 3).

**Regarding claim 15**, Perrier et al. disclose the implant according to claim 13, wherein the at least one flap is substantially non-planar with a surface of the tubular wall (fig. 5).

**Regarding claim 16**, Perrier et al. disclose the implant according to claim 13, wherein the at least one flap is positionally adjustable (figs. 3, 5).

7. **Claims 13, 18 and 19** are rejected under 35 U.S.C. 102(b) as being anticipated by **Latac et al. (US 2001/0010017 A1)**.

**Regarding claim 13**, Latac et al. disclose an implant for obstructing blood flow in a blood vessel, the implant comprising: a tubular wall (10) defining a flow passage adapted for encircling a flow of blood through a vessel; and at least one non-overlapping flap (14) projecting from the wall into the blood vessel (figs. 5a-b).

**Regarding claim 18**, Latac et al. disclose the implant according to claim 13, comprising a kit ([0141]) that additionally includes a flap angle adjusting tool, the tool comprising a shaft (27f) having one or more wing projections (26) adapted to press against one or more flow obstructing flaps (figs. 13a-l).

**Regarding claim 19**, Latac et al. disclose the implant according to claim 18, wherein the one or more wings of the tool are activated inflatably (fig. 13h).

8. **Claims 30 and 32-35** are rejected under 35 U.S.C. 102(b) as being anticipated by **Bozzo (EP 0355341 B1)**.

**Regarding claim 30**, Bozzo discloses a method of modifying an implant geometry, of a tubular implant with at least one intra-luminal flap (2), comprising: contacting at least one intra-lumen flap of an implanted vascular implant with an effector element (19); and bending said flap by applying force via said contact (figs. 8, 9).

**Regarding claim 32**, Bozzo discloses the method according to claim 30, wherein contacting comprises pushing said element towards said flap (figs. 8, 9).

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**Regarding claim 33**, Bozzo discloses the method according to claim 32, wherein pushing comprises enough force to tear an element restraining (20) of said flap ((2); column 5, lines 24-28).

**Regarding claims 34 and 35**, Bozzo discloses the method according to claim 30, wherein said element comprises a mechanically expandable element ((19); column 5, lines 24-28).

9. **Claims 36-39** are rejected under 35 U.S.C. 102(b) as being anticipated by **Andersen et al. (US 6,168,614 B1)**.

**Regarding claim 36**, Andersen et al. disclose an implant comprising: a radially expandable tubular sheath (fig. 1); and at least one flap (4) welded to said sheath and configured to at least partially and rigidly obstruct a lumen of said sheath.

**Regarding claim 37**, Andersen et al. disclose the implant according to claim 36, wherein said tubular sheath comprises a wire mesh sheath (fig. 1; column 4, lines 66-67).

**Regarding claim 38**, Andersen et al. disclose the implant according to claim 36, comprising at least two flaps (4) and comprising at least one restraining element (13) interconnecting said flaps and limiting their movement relative to each other (fig. 4).

**Regarding claim 39**, Andersen et al. disclose the implant according to claim 38, wherein said restraining element is adapted to be torn by applying force to one or more flaps, while implanted (column 6, lines 15-21). It has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only

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requires the ability to so perform. It does not constitute a limitation in any patentable sense.

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. **Claims 31** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Bozzo (EP 0355341 B1)**.

**Regarding claim 31**, Bozzo discloses the invention except for wherein contacting the flap comprises pulling said element towards said flap.

However, Bozzo teaches wherein contacting comprises pushing said element towards said flap (figs. 8, 9).



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Given the teachings of Bozzo, it would have been obvious to one of ordinary skill in the art at the time of the invention to pull rather than push the element towards the flap. Doing so would allow for a smaller inner diameter between the flaps, allowing the device to reach smaller treatment sites.

### ***Conclusion***

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SARAH A. SIMPSON whose telephone number is 571-270-3865. The examiner can normally be reached on Monday - Friday 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sarah A Simpson/  
Examiner, Art Unit 3731

/Todd E Manahan/  
Supervisory Patent Examiner, Art Unit 3731